

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. DISPOSITION OF THE CLAIMS

Claims 7-9 and 16-17 are currently being amended. No new matter has been added. The specification supports the amendment to claim 7 (“correlating...” at paragraphs [0016] and [0054] and supports the amendment to claim 9 at paragraph [0026] (citing to published application US 2007-0275880).

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-9 and 11-18 are now pending in this application. Claims 1-6, 11-15, and 18 are withdrawn as non-elected. Claims 7-9 and 16-17 are under examination.

II. CLAIM OBJECTIONS

Applicants have obviated the objections to claims 7 and 16-17 by spelling out “vWF” in claim 7 and by eliminating “ore” in claims 16-17.

III. INDEFINITENESS

Regarding claim 7, the Office questioned whether the recited solution contains FVIII. Applicants have obviated this issue by amending claim 7 to recite “filtering a solution comprising FVIII”.

Regarding the meaning of “high-multimerization”, a person of ordinary skill in the art would readily understand this phrase. Applicants refer the Office to paragraph [0010]

(reproduced below) of published application US 2007-0275880 and the reference Metzner cited therein and submitted in an Information Disclosure Statement filed September 23, 2008:

[0010] Depending upon the FVIII purification methods used, the end product may contain vWF at varying degrees of multimerisation (METZNER, HERMENTIN et al—Haemophilia (1998), 4 (Suppl 0.3), 25-32.

Regarding the relationship between “assaying the filtrate to determine high multimerization vWF” and “virally safe FVIII solution”, a person of ordinary skill in the art would readily understand this phrase. Applicants refer the Office to paragraph [0016] and Table V (page 4) (reproduced below) of the published application:

[0016] In surprising, unexpected manner we have found that the reduction of high molecular weight vWF multimers, measured in the filtrates of FVIII, correlates with the efficacy of virus retention by the filter. In addition, by verifying multimer content, we have discovered that it is possible to filter at approximately 20 nm. We therefore propose a new means for the high yield production and characterisation of FVIII which meets the requirements of virus removal by nanometric filtration.

TABLE V

<u>Correlation between viral reduction factor (Rf) and >10 mer vWF multimer composition.</u>								
	<u>Example 1</u>		<u>Example 2</u>		<u>Example 3</u>		<u>Example 4</u>	
	Before	After	Before	After	Before	After	Before	After
Multimers 10-15	15%	9%	13%	10%	13%	8%	27%	12%
Multimers 16+	11%	4%	10%	2%	10%	7%	10%	6%
Total	26%	13%	23%	12%	23%	15%	37%	18%
Virus reduction factor (log)	6.0		4.3		6.1		2.1	

Regarding claims 9 and 16-17, the Office questioned the recitation of “nm”. Applicants have obviated this issue by amending claim 9 to recite “a virus having a size diameter of 24 nm to 30 nm”.

Regarding how vWF decamer and higher multimer content less than 15% indicates titre reduction factor of 4 log to 6 log, a person of ordinary skill in the art would readily understand from the disclosures in the specification. Applicants refer the Office to paragraphs [0051] and [0055] of the published application and to the Examples as summarized in Table V. Paragraphs [0052] – [0053] and [0055] of the published application state:

[0052] Table V groups together the sum of multimer values from the decamer. It is found that: when the sum of vWF decamers and higher multimers is no more than 15%, the reduction in virus titre is always >4 log.

[0053] On the other hand, if this sum exceeds 16%, the reduction in viral titre is less than 4 log.

[0055] The virus retention efficacy of >4 log is therefore related to a distribution of vWF multimers in the filtrate of no more than 15% multimers of multimerisation >10. These data are summarized in Table V:

TABLE V

<u>Correlation between viral reduction factor (Rf) and >10 mer vWF multimer composition.</u>								
	<u>Example 1</u>		<u>Example 2</u>		<u>Example 3</u>		<u>Example 4</u>	
	Before	After	Before	After	Before	After	Before	After
Multimers 10-15	15%	9%	13%	10%	13%	8%	27%	12%
Multimers 16+	11%	4%	10%	2%	10%	7%	10%	6%
Total	26%	13%	23%	12%	23%	15%	37%	18%
Virus reduction factor (log)	6.0		4.3		6.1		2.1	

Regarding claim 17, the Office questioned the titre reduction factor limitation. Applicants have appropriately amended claim 17 to recite “the titre reduction factor of a virus having a size of 24 nm to 30 nm is ~~6 log or more~~, to about 6 log”.

IV. ANTICIPATION

The claims stand rejected as anticipated based on US 6,967,239 (“Chtourou”). Applicants respectfully traverse.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” M.P.E.P. § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987)). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” M.P.E.P. § 2143.03, quoting *In re Wilson*, 424 F.2d 1382, 1385 (C.C.P.A. 1970).

Claim 7 as amended recites and “correlating the residual content of high multimerization vWF with viral safety”. Chtourou fails to satisfy this limitation. Chtourou fails to disclose any step of correlating residual content of high multimerization vWF and viral safety. Chtourou otherwise provides no indication that such a correlation exists.

Chtourou thus could not anticipate claim 7. Further, Chtourou could not anticipate claims 8-9 and 16-17, because these depend from claim 7.

Applicants note that case law supports the patentability of claims with such “correlating” steps. See *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 92 U.S.P.Q.2d 1075 (Fed. Cir. 2009); *Metabolite Labs., Inc. v. Lab. Corp.*, 370 F.3d 1354, 71 U.S.P.Q.2d 1081 (Fed. Cir. 2004) (cert. dismissed, 548 U.S. 124, 126 S.Ct. 2921 (2006)). The *Metabolite* case is particularly notable, because the Federal Circuit affirmed validity of a claim reciting “correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate” and the Office affirmed the *Metabolite* claims after reexamination (see Reexamination Control No. 90/008,305).

Accordingly, this ground of rejection should be withdrawn.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By 

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